



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/808,872	03/24/2004	Mian Ying Wang	10209.476	6611

7590 07/31/2006
KIRTON & McCONKIE
Suite 1800
60 East South Temple
Salt Lake City, UT 84111

EXAMINER

LEITH, PATRICIA A

ART UNIT PAPER NUMBER

1655

DATE MAILED: 07/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/808,872

Applicant(s)

WANG ET AL.

Examiner

Patricia Leith

Art Unit

1655

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 5/5/06.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-60 is/are pending in the application.
- 4a) Of the above claim(s) 12-60 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-60 are pending in the application.

Election/Restrictions

Applicant's election without traverse of Group I, claims 1-11 in the reply filed on 5/5/06 is acknowledged. Applicant inadvertently omitted the election of species. During a telephone conversation with Michael Krieger and Jerod Marrott on 7/11/06, a provisional election was made with traverse to prosecute the Species of *Morinda citrifolia* leaf extract. Affirmation of this election must be made by applicant in replying to this Office action. .

Claims 12-60 are thus hereby withdrawn from the merits as being directed toward a non-elected invention.

Claims 1-11 were examined on their merits with regard to the species of *Morinda citrifolia* leaf extract.

It is noted that *Morinda citrifolia* may be referred to herein as 'MC'.

Specification

The disclosure is objected to because of the following informalities: Pages 22 and 23 of the Specification contain figures which should be presented as official Drawings. Upon presentation of the figures as Drawings, the Specification should be amended to include a Brief Description of the Drawings which does not introduce New Matter into the disclosure.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 states 'the method comprising providing for use a dietary supplement'. This statement is ambiguous in that the Examiner cannot clearly delineate what

Art Unit: 1655

Applicant intends to claim. Does this statement mean that the dietary supplement is administered to a patient? The Examiner cannot be absolutely sure based upon this language present in the claim. Because the ordinary artisan would not be able to ascertain whether they were in possession of the method of claim 1, this claim is rendered indefinite.

Claims 3 and 10 recite 'the step for providing a recommended use of the dietary supplement'. This statement is also confusing. Does applicant mean that the method further comprises the steps of the claim, or are the steps of the claims present on a type of printed information? The Examiner cannot clearly determine the metes and bounds of the claim limitations and therefore these claims are indefinite.

Claims 4 and 11 also recite 'wherein the recommended use further includes'. Again, does Applicant mean that the method step in these claims are actually carried out, or is printed on a label?

Because claims 2 and 5-6 and 11 depend directly or indirectly upon claims 1 or 7 respectively, these claims necessarily possess all of the limitations of the rejected claims (respectively) and are thus also indefinite because they do not remedy the indefiniteness of the above-rejected claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-8 and 10-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Rosenbloom-Kerzner (2002)..

Rosenbloom-Kerzner (2002) reporting for The Post – Tribune indicated that MC leaf extract was known and was consumed for various medicinal purposes (see pp. 1-2). Although the reference does not explicitly state wherein the extract was consumed for inhibiting estrogen production, it is deemed that this would have been an inherent consequence of ingestion of the MC leaf extract.

Claim 3 states that one ounce or more than one ounce or less than one ounce of the MC extract is consumed. The product described by Rosenbloom-Kerzner (2002) must have been consumed at one of these doses, as these doses cover all potential dosages. Further, it is deemed that the dosage of MC leaf extract was taken before a meal. These claims, claims 4 and 11 simply state that wherein the recommended use provides for consuming the dietary supplement before a meal. It is deemed that there is

Art Unit: 1655

no specific time-limit set forth in the claims. Therefore, the MC leaf extract of the prior art must have been taken before a meal, even if it was minutes, hours or days prior to a meal.

Claims which state using the dietary supplement as an 'aromatase inhibitor' or 'to provide estrogenic effects in the body' does not functionally change the method of the claimed invention. It is deemed that the because the product of the prior art and the product of the claims are the same, that the composition would have inherently performed these characteristics and are therefore anticipated by the prior art.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rosenbloom-Kerzner (2002) in view of Flockhart et al. (WO 9307901 A1).

The teachings of Rosenbloom-Kerzner (2002) were discussed *supra*. Rosenbloom-Kerzner (2002) did not specifically teach wherein the MC leaf extract was present in a dermal composition.

Flockhart et al. (WO 9307901 A1) taught methods for the systemic transdermal delivery of medicinally active plant extracts (see for example, page 1, last three paragraphs, page 4, last two paragraphs and page 6, last paragraph).

Thus, although the prior art did not specifically teach wherein the MC leaf extract was present in a dermal composition, formulating active ingredients into varying delivery vehicles was routine in the art at the time the invention was made as indicated by Flockhart et al.. Transdermal delivery is well known in the art as a means for transporting active agents across the dermal layers and into the bloodstream. Therefore, the mere addition of a known, medicinally active ingredient into a topical formulation is considered obvious.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia Leith whose telephone number is (571) 272-0968. The examiner can normally be reached on Monday - Friday 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Patricia Leith
Primary Examiner
Art Unit 1655

July 13, 2006

A handwritten signature in cursive script, appearing to read 'Patricia Leith', written in black ink.